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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,381	03/19/2004	Scott Edward Osborne	7892C	7237

27752 7590 12/20/2006
THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
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EXAMINER

CHANNAVAJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/804,381

Applicant(s)

OSBORNE ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 9-22-06 is acknowledged.

Claims 1-9 and 11-19 are pending in the instant application.

The following rejections of record have been maintained:

1. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,716,441.

2. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,153,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons: The patented claims directed to an article and a method of effectively delivering one or more skin care actives and is generic to various skin active agents, surfactants, emollients, etc., all of which are claimed in the instant application. The patented claims also recite the claimed chitosan, emollients, surfactants, barrier protectants (claimed as immobilizing agents) etc., thus anticipating instant claims.

Claims directed to an invention not patentably distinct from claims 1-32 of commonly assigned US 6,153,209.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP

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Chapter 2300). Commonly assigned 6,153,209, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

3. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,643,588 to Roe in view of US 6,562,802 to Johansson et al.

Roe teaches a diaper (reads on the instant article), comprising a lotioned topsheet, wherein the lotion composition is a semisolid or a solid at 20degrees C and is adapted to be transferred to the wearer's skin (as claimed, col. 9-10). The lotion of Roe comprises emollients (read on claimed protectants) such as petrolatum, fatty acid ester, fatty alcohols, polysiloxanes, waxes etc (col. 11-12); immobilizing agents (cols. 13-16), surfactants (col. 16-18), including those having HLB value in the claimed range. For paraffin wax, see example 6 and claim 19. Roe further teaches incorporating active

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agents such as pharmaceutical or antibacterial active agents in the lotion, particularly therapeutic agents (Col.18). Roe fails to teach the claimed chitosan.

Johansson teaches topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). The components urea, lactic acid, paraffin liquid and polyoxyethylene-2-stearyl-ether read on the claimed skin protectant, pH control agent, and barrier protectant and release agent respectively. Johansson teaches skin composition containing chitosan in the form of cream, lotion or gel and suggests the addition of an amine- containing polymer, chitosan, for successful binding of antiallergenic substances such as EDTA (meets limitation of claim 4)(col. 8). Johansson teaches that the chitosan polymer forms a barrier protection and prevents contact of skin with the allergens or other irritants. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add chitosan and anti-allergens such as EDTA of Johansson to the lotion composition applied to a diaper (of Roe) because Johansson suggests that chitosan has superior features to make it a skin or mucus membrane protector when combined with an anti-allergen and is very effective in protecting skin during therapeutic treatments with anti-viral, anti-bacterial treatment or for UV protection (col. 6 and 8). Roe and Johansson suggest various percentages or amounts of the claimed components that fall within the claimed ranges and accordingly, optimizing the amounts of the same so as to achieve the optimum release of the active agent to skin and at the

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same time provide barrier protection to skin from irritants or allergens would have been within the scope of a skilled artisan.

Response to Arguments

Double patenting rejection:

In response to the double patenting rejections, applicants agreed to file necessary terminal disclaimers upon indicating the allowable subject matter. However, at this time no allowable subject matter has been identified and accordingly, the rejection has been maintained.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,643,588 to Roe in view of US 6,562,802 to Johansson et al.

Applicants argue that Roe does not desire chitosan and Johansson fails to teach neither paraffin wax nor desires paraffin wax. Therefore, it is argued that there is no motivation to combine the references and that obviousness cannot be established by combining the teachings of the prior art absent any teachings or motivation. Applicants argue that Roe and Johansson are two disparate disclosures and nothing in Roe would prompt the skilled person to consider the desirability of chitosan as a skin care active ingredient of the lotion for baby diapers. It is argued there is no motivation to modify the medical composition of Johansson to choose one of many to be combined with the components of Roe, directed to baby diapers. It is argued that Johansson seventeen (17) different ingredients from which the skilled person could choose as an antiallergenic compound. It is also argued that Johansson focuses on the severe condition of hand eczema and not of baby diapers.

With respect to the argument regarding paraffin wax, it is not required that all the cited references disclose each and every component of the instant claims. Roe teaches paraffin wax and the claimed release agents as emollients and immobilizing agents in the barrier protection formulation. Applicants' arguments regarding chitosan are not persuasive because both Roe and Johansson teaches skin protecting compositions, which impart barrier protection on the skin and thus constitute analogous art.

Johansson teaches an effective barrier protection formulation for the treatment of dermatological disorders induced by allergens and skin irritating agents. Thus, the teachings of Johansson include compositions effective against skin irritating agents in general, even though the reference cites cobalt or nickel specifically. In this regard, while Roe desires that the barrier protection composition reduces the affinity of the bowel wastes to the skin and thus their contact with the skin, Roe does not teach that the contact of these bowel materials cause skin dermatitis. However, the fact that these materials can cause diaper dermatitis is well recognized in the art (see col. 2, L 61-67 of US patent No. 4,673,402).

In contrast to applicants' argument that chitosan is not recognized for its skin care activity, Johansson teaches chitosan polymer as a skin protector (col. 8, L 51-col. 10, L 25), a function also desired by Roe. Further, examiner notes that instant claims do not recite any specific skin care activity by chitosan nor does the instant specification provide any definition with respect to the term skin care and therefore, the skin protecting effect of chitosan taught by Johansson reads on the instant skin care. In this regard, examiner cites the teachings of JP 05228176 (abstract) that recognizes the

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antibacterial activity of chitosan on hygiene products such as diapers. Thus, the chitosan of Johansson functions as a barrier protectant and also possess antibacterial properties (skin care). Thus, the motivation to include chitosan of Johansson in the skin barrier protection composition of Roe comes from the skin barrier protecting effect of chitosan. The expected result is to protect skin from contacting with the bowel waste material. With respect to the argument that Johansson fails to teach the dispensing means and the method of application (claims 14-19), Roe clearly teaches the claimed dispensing means. Therefore, the rejection has been maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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December 18, 2006


LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER